CLAIMS

1. A method for preparing a sterile composition of a pharmaceutical compound comprising combining solvent with a non-sterile pharmaceutical compound to yield a sterile pharmaceutical compound, optionally removing all or part of the solvent, and under sterile conditions combining the compound with a pharmaceutically acceptable carrier.

2. A method according to Claim 1 wherein the non-sterile pharmaceutical compound is a powder.

3. A method according to Claim 2 wherein the powder is a micronized powder.

4. A method according to any of Claims 1 to 3 wherein the compound is a steroid.

5. A method according to Claim 4 wherein the compound is budesonide or fluticasone.

6. A method according to any of Claims 1 to 5 wherein the solvent comprises an alcohol.

7. A method according to any of Claims 1 to 5 wherein the solvent comprises a Class 3 solvent.

8. A method according to any of Claims 1 to 5 wherein the solvent comprises a Class 2 solvent.

9. A method according to any of Claims 1 to 8, comprising combining solvent with the compound at an elevated temperature, suitably from 20°C below the boiling point of the solvent up to its boiling point.

10. A method according to Claim 9 wherein the solvent is at reflux.

11. A method according to any of Claims 1 to 8 wherein the solvent is at 30-50°C.

12. A method according to any of Claims 1 to 11, comprising using sufficient solvent to obtain a slurry of the compound.

13. A method according to any of Claims 1 to 12, comprising removing solvent under reduced pressure.

14. A method according to any of Claims 1 to 12 comprising removing solvent at atmospheric pressure.

15. A method according to any of Claims 1 to 14, comprising removing solvent to yield an essentially solvent-free powder.

16. A method according to any of Claims 1 to 15, comprising using sufficient solvent to obtain a solution of the compound.

17. A method according to Claim 16 comprising filtering the solution.

18. A method according to Claim 17 using a filter having a pore size of 0.2μm or less.

19. A method according to any of Claims 1 to 18, comprising combining the sterile pharmaceutical compound with water to form a suspension.

20. A method according to Claim 19, wherein the water contains surfactant.

21. A method according to Claim 19 or 20, comprising removing solvent from the suspension.

22. A method according to Claim 21, wherein solvent is removed under reduced

pressure.

23. A method according to Claim 21, wherein solvent is removed at atmospheric pressure.

24. A method according to any of Claims 19 to 23, comprising treating the suspension to obtain a particle size distribution having a mass median diameter less than 10μm.

25. A method according to Claim 24, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 1-5μm.

26. A method according to Claim 24, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 2-3μm.

27. A method according to any of Claims 24 to 26, comprising storing the sterile composition in sterile containers.

28. A method according to Claim 27, comprising storing the sterile composition in sterile ampoules.

29. A method for preparing a sterile composition of a pharmaceutical compound comprising combining solvent with a non-sterile pharmaceutical compound so as to form a solution and filtering the solution to yield a sterile solution of the pharmaceutical compound.

30. A method according to Claim 29 wherein the non-sterile pharmaceutical compound is a powder.

31. A method according to Claim 30 wherein the powder is a micronized powder.

32. A method according to any of Claims 29 to 31 wherein the compound is a

steroid.

33. A method according to Claim 32 wherein the compound is budesonide or fluticasone.

34. A method according to any of Claims 29 to 33 wherein the solvent comprises an alcohol.

35. A method according to any of Claims 29 to 33 wherein the solvent comprises a Class 3 solvent.

36. A method according to any of Claims 29 to 33 wherein the solvent comprises a Class 2 solvent.

37. A method according to any of Claims 29 to 36, comprising combining solvent with the compound at an elevated temperature, suitably from 20°C below the boiling point of the solvent up to its boiling point.

38. A method according to Claim 37 wherein the solvent is at reflux.

39. A method according to any of Claims 29 to 36 wherein the solvent is at 30-50°C.

40. A method according to any of Claims 29 to 39, comprising removing solvent from the sterile solution under reduced pressure.

41. A method according to any of Claims 29 to 39 comprising removing solvent from the sterile solution at atmospheric pressure.

42. A method according to any of Claims 29 to 41, comprising removing solvent from the sterile solution to yield a solvent-free powder.

43. A method according to Claim 42 using a filter having a pore size of 0.2μm or

less.

44. A method according to any of Claims 29 to 43 comprising combining the sterile solution of the pharmaceutical compound with water to form a suspension.

45. A method according to Claim 44, wherein the water contains surfactant.

46. A method according to Claim 44 or 45, comprising removing solvent from the suspension.

47. A method according to Claim 46, wherein solvent is removed under reduced pressure.

48. A method according to Claim 46, wherein solvent is removed at atmospheric pressure.

49. A method according to any of Claims 44 to 48, comprising treating the suspension to obtain a particle size distribution having a mass median diameter less than 10μm.

50. A method according to Claim 49, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 1-5μm.

51. A method according to Claim 49, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 2-3μm.

52. A method according to any of Claims 49 to 51, comprising combining the sterile composition with a carrier.

53. A method according to any of Claims 49 to 52, comprising storing the sterile composition in sterile containers.

54. A method according to Claim 53, comprising storing the sterile composition in sterile ampoules.

55. A method for preparing a sterile composition of a pharmaceutical compound comprising combining solvent with a suspension of a non-sterile pharmaceutical compound to yield a sterile suspension of a pharmaceutical compound, removing solvent, and under sterile conditions combining the sterile suspension with a pharmaceutically acceptable carrier.

56. A method according to Claim 55, wherein the compound is a steroid.

57. A method according to Claims 55 or 56, wherein the solvent comprises an alcohol.

58. A method according to Claim 55 or 56, wherein the solvent comprises a Class 3 solvent.

59. A method according to Claim 55 or 56, wherein the solvent comprises a Class 2 solvent.

60. A method according to any of Claims 55 to 59, comprising combining solvent with the compound at an elevated temperature, suitably not less than 20°C below its boiling point.

61. A method according to any of Claims 55 to 59, wherein solvent is at 30-50°C.

62. A method according to any of Claims 55 to 61, comprising removing solvent under reduced pressure.

63. A method according to any of Claims 55 to 61, comprising removing solvent at atmospheric pressure.

64. A method according to any of Claims 55 to 63, wherein the suspension contains a surfactant.

65. A method according to any of Claims 55 to 64, comprising treating the suspension to obtain a particle size distribution having a mass median diameter less than 10μm.

66. A method according to Claim 65, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 1-5μm.

67. A method according to Claim 65, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 2-3μm.

68. A method according to any of Claims 65 to 67, comprising storing the sterile suspension in sterile containers.

69. A method according to Claim 68, comprising storing the sterile suspension in sterile ampoules.

70. A sterile composition prepared according to the method of any of Claims 1 to 69.

71. A sterile composition according to Claim 70 wherein the composition is a suspension.

72. A sterile powder prepared according to any of Claims 1 to 15.

73. A sterile powder prepared according to any of Claims 40 to 42.

74. Apparatus for preparing a sterile composition of a pharmaceutical compound, comprising a container defining a sterile inner compartment, a first vessel

containing a solvent, and a second vessel containing a non-sterile pharmaceutical compound, arranged so that the solvent can be combined with the non-sterile compound to yield a sterile compound within the compartment, the compartment also containing a sterile aqueous solution into which the sterile compound can be introduced to form a sterile suspension, optionally an apparatus for alteration of the particle size distribution of the suspension and further optionally a sterile exit line for transfer of sterile suspension to sterile containers.

75. Apparatus according to Claim 74, further comprising a sterile filter.

76. Apparatus according to Claim 75, wherein the sterile filter has a pore size of 0.2μm or less.